510(k) Summary

APR 0 1 2013

I. General Information

a. Submitter Information

Submitter's Name and Address	Medtronic, Inc. Medtronic Cardiovascular 8200 Coral Sea Street NE, MVS83 Mounds View, MN 55112
Contact Person	Kari Christianson Senior Regulatory Affairs Specialist Tel: 763-514-9529 FAX: 763-367-9827 Email: kari.j.christianson@medtronic.com
Date of Summary	December 04, 2012
Proprietary Name of Device	Cardioblate® CryoFlex® Surgical Ablation System
Common/Usual Name	Cryosurgical System
Classification Name	Surgical Device, for Ablation of Cardiac Tissue
Classification	Class II, per 21 CFR 878.4350
Product Code:	OCL
Predicate Device	Cardioblate® CryoFlex® Surgical Ablation System (K121878)

II. Device Description

a. System and Components

The Medtronic Cardioblate® CryoFlex® Surgical Ablation Probes, Console, and accessories are used together as a system. The system is composed of the following components:

Components	Model number
Cardioblate CryoFlex Console	65CS1
Cardioblate CryoFlex Console, Refurbished	R65CS1
Cardioblate CryoFlex 7cm Probe	60SF7
Cardioblate CryoFlex 10cm Probe	60SF2
Cardioblate CryoFlex 10S Probe	60SF3
Cardioblate CryoFlex Clamp with 10cm Probe	60CM1
Tank Carrier	65TC1
Tank Regulator	67RAXNA
Tank Regulator, Refurbished	R67RAXNA
Pressure Transducer Cable, 6ft. (1.8m)	67PS6
Gas Hose, 8ft (2.4m)	67H08
Power Cord, North American	671PCNA

b. System Overview

The Medtronic Cardioblate CryoFlex Surgical Ablation System is a cryoablative surgical device that is used in the cryosurgical treatment of cardiac arrhythmias. The system utilizes an argon-based cryogen for fast, controlled freezing.

The Cardioblate CryoFlex probes are single use, disposable cryoprobes that are designed for use with the system. Each probe has an integrated thermocouple for monitoring temperature at is ablation segment. The probes are supplied sterile, cannot be reused or re-sterilized, and are available in 7cm, 10cm, 10-S (slightly stiffer), and clamp with 10cm probe versions.

The probes shaft and ablation segment are made of specially heat-treated stainless steel. The shaft was designed with enough malleability that the surgeon can easily shape it while still maintaining enough stiffness to ensure its stability in the operating field.

The malleable ablation segment has a bellows configuration, which provides kink resistance and thermal performance. A movable insulative sleeve on the shaft allows the surgeon to vary the size of the ablation zone.

The probe has a 3m (10ft) connection hose which is to be handed out of the sterile field to an operating room nurse for connection to the control panel. Note that once the probe is connected to the control panel, it should not be disconnected until the end of the procedure because it cannot be reconnected. The probe is disabled once it is disconnected.

III. Indications for Use

The Cardioblate CryoFlex Surgical Ablation System is intended for minimally invasive cardiac surgical procedures, including the treatment of cardiac arrhythmias. The Cardioblate CryoFlex 7 cm, 10 cm, and 10-S probes plus the Clamp and Surgical Ablation Console freeze target tissue and block the electrical conduction pathways by creating an inflammatory response and cryonecrosis.

There is no change to the indications for use as compared to the predicate device.

IV. Comparison to Predicate Devices

The Medtronic Cardioblate CryoFlex Surgical Ablation system is substantially equivalent to the predicate surgical ablation system, has the same intended use and the same design with the exception of the addition of an alternate insulative sheath component on the 7cm, 10cm and 10S probes (Models 60SF7, 60SF2, and 60SF3, respectively) and on the clamp with 10cm probe (Model 60CM1).

V. Summary of Performance Data

Verification and validation testing has demonstrated that the Medtronic Cardioblate CryoFlex Surgical Ablation System is substantially equivalent to the predicates.

VI. Conclusion

Based on the accumulated technical information, intended use, verification tests and performance data provided, the Cardioblate CryoFlex Surgical Ablation system is substantially equivalent to the currently marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 1, 2013

Medtronic Inc.
c/o Ms. Kari Christianson
Senior Regulatory Affairs Specialist
8200 Coral Sea Street NE, Mail Stop MVS83
Mounds View, MN 55112

Re: K123733
Trade/Device Name: Cardioblate CryoFlex Surgical Ablation System
Regulation Number: 21 CFR 870.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories.
Regulatory Class: II
Product Code: OCL
Dated: February 6, 2013
Received: February 8, 2013

Dear Ms. Christianson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Cardioblate® CryoFlex® Surgical Ablation System

Indications For Use: The Cardioblate CryoFlex Surgical Ablation System is intended for minimally invasive cardiac surgical procedures, including the treatment of cardiac arrhythmias. The Cardioblate CryoFlex 7 cm, 10 cm, and 10-S probes plus CryoFlex Clamp and Surgical Ablation Console freeze target tissue and block the electrical conduction pathways by creating an inflammatory response and cryonecrosis.

Prescription Use ___X___ AND/OR Over-The-Counter Use ___

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Bram D. Zuckerman
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